

Dated: January 16, 2015.
Leslie Kux,
Associate Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0915]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the FDA guidance for industry on “Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application.” This guidance document provides recommendations on postmarketing serious adverse event reporting for nonprescription (over-the-counter) human drugs marketed without an approved application. It provides recommendations on the minimum data elements that should be included in a serious adverse event report, the label that should be included with the report, reporting formats for paper and electronic submissions, and how and where to submit the reports.

DATES: Submit either electronic or written comments on the collection of information by March 24, 2015.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA 305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and

assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry on Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application (OMB Control Number 0910-0636)—Extension

Respondents to this collection of information are manufacturers, packers, and distributors whose name (under section 502(b)(1) (21 U.S.C. 352(b)(1)) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act)) appears on the label of a nonprescription drug marketed in the United States. FDA is requesting public comment on estimates of annual submissions from these respondents, as required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Pub. L. 109-462) and described in the guidance. The guidance document discusses what should be included in a serious adverse drug event report submitted under section 760(b)(1) (21 U.S.C. 379aa(b)(1)) of the FD&C Act, including follow-up reports under 760(c)(2) (21 U.S.C. 379aa(c)(2)) of the FD&C Act, and how to submit these reports. The estimates for the annual reporting and recordkeeping burdens are based on FDA data on the number of adverse drug experience reports submitted for nonprescription drug products marketed without an approved application, including FDA’s knowledge about the time needed to prepare the reports and to maintain records.

Based on FDA data, we estimate between 10,000 and 15,000 (*i.e.*, approximately 12,500) total annual responses from approximately 50 respondents for nonprescription drugs marketed without an approved application, and we also estimate that each submission will take approximately 2 hours to prepare and submit.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Reports of serious adverse drug events (21 U.S.C. 379aa(b) and (c))	50	250	12,500	2	25,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Section 760(e) (21 U.S.C. 379aa(e)) of the FD&C Act also requires that responsible persons maintain records of nonprescription adverse event reports, whether or not the event is serious, for a period of 6 years. The guidance

document recommends that respondents maintain records of efforts to obtain the minimum data elements for a report of a serious adverse drug event and any follow-up reports. We estimate that there are approximately

20,000 records per year maintained by approximately 200 respondents, and that it takes approximately 5 hours to maintain each record.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping (21 U.S.C. 379aa(e)(1))	200	100	20,000	5	100,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Therefore, the estimated annual reporting burden for this information is 25,000 hours and the estimated annual recordkeeping burden is 100,000 hours.

Dated: January 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Request for Nominations for Voting Members on a Public Advisory Committee; Science Board to the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for members to serve on the Science Board to the Food and Drug Administration, Office of the Commissioner, Office of the Chief Scientist. FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received on or before March 24, 2015 will be given first consideration for membership on the Science Board to the Food and Drug Administration. Nominations received after March 24, 2015 will be considered for nomination to the committee as later vacancies occur.

ADDRESSES: All nominations for membership should be sent electronically by logging into the FDA Advisory Nomination Portal: [http://](http://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm)

www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002.

FOR FURTHER INFORMATION CONTACT:

Regarding all nomination questions for membership, the primary contact is: Martha Monser, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3309, Silver Spring, MD 20993-0002, 301-796-4627, martha.monser@fda.hhs.gov.

Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site by using the following link: <http://www.fda.gov/AdvisoryCommittees/default.htm>.

SUPPLEMENTARY INFORMATION: FDA is requesting nomination for voting members on the Science Board to the Food and Drug Administration.

I. General Description of the Committee Duties

The Science Board shall provide advice to the Commissioner and other appropriate officials on specific complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board will provide advice that supports the Agency in keeping pace with technical and scientific developments, including in regulatory science, provide input into the Agency's research agenda, and on upgrading its scientific and research facilities and training opportunities. It will also provide, where requested, expert review of Agency sponsored intramural and extramural scientific research programs.

II. Criteria for Voting Members

The committee consists of a core of 21 voting members including the chair and a co-chair. Members, the chair and the

co-chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of: Food science, safety, and nutrition; chemistry, pharmacology, translational and clinical medicine and research, toxicology, biostatistics, medical devices, imaging, robotics, cell and tissue based products, regenerative medicine, public health and epidemiology, international health and regulation, product safety, product manufacturing sciences and quality; and other scientific areas relevant to FDA regulated products such as systems biology, informatics, nanotechnology, and combination products. Almost all non-Federal members of this committee serve as Special Government Employees. Members will be invited to serve for terms of up to 4 years.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the advisory committee. Self-nominations are also accepted. Nominations must include a current, complete resume or curriculum vitae for each nominee, including current business address and/or home address, telephone number, and email address if available. Nominations must also specify the advisory committee for which the nominee recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.